K062651

510(k) Summary of Safety and Effectiveness

510(k) Notification
ProChem EXT – Chemical Integrator

MAR 15 2007

Submitted by:	Raven Biological Laboratories 8607 Park Drive Omaha, NE 68127
Contact:	Wendy Royalty-Hann Quality Assurance/Regulatory Affairs Manager Or Robert V. Dwyer, Jr. President Phone: (402) 593-0781 Fax: (402) 593-0921
Prepared on:	May 3, 2006
Device:	Trade name: ProChem EXT Chemical Integrator Common name: Physical/chemical sterilization process indicator
Classification:	Class II
Predicate Device:	TST Control Integrator for Steam Autoclave 510(k) #K965154, K002937 & K902958

DEVICE DESCRIPTION

ProChem EXT is a 16 mm x 97 mm strip with a 2 mm x 77 mm chemical indicator ink strip printed below a reference triangle exhibiting the endpoint color.

INTENDED USE

ProChem EXT is an integrating indicator that changes color from green to black when exposed to the following conditions:

- 121°C, 20 min., steam sterilizers
- 132°C, 8.5 min., steam sterilizers
- 134°C, 7.5 min., steam sterilizers
- 135°C, 7 min., steam sterilizers

TECHNOLOGICAL CHARACTERISTICS

The ProChem EXT consists of a paper strip printed with a chemical indicator ink. A chemical reaction occurs changing the ink color from green to black when exposed to the critical parameters of a steam sterilization process.

PERFORMANCE TESTING AND SUBSTANTIAL EQUIVALENCE

Performance testing was conducted in accordance with ANSI/AAMI ST 60 – 1996 in an AAMI compliant steam resistometer using 3 separate production lots of chemical integrators. The performance of the ProChem EXT was equivalent to that of the predicate device and meets the requirements of Class 5 indicators as defined in clauses 9.1 and 9.3 of ANSI/AAMI ST60:1996.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2007

Ms. Wendy Royalty-Hann
Quality Assurance/Regulatory Affairs Manager
Raven Biological Laboratories, Incorporated
8607 Park Drive
Omaha, Nebraska 68127

Re: K062651
Trade/Device Name: ProChem EXT Chemical Integrator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 26, 2007
Received: February 27, 2007

Dear Ms. Royalty-Hann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K062651

Device Name ProChem EXT Chemical Integrator

Indications for Raven ProChem EXT chemical integrator is an integrating chemical indicator intended for monitoring the efficacy of steam sterilization cycles, gravity displacement at 121°C, 20 minutes and prevacuum cycles: 121°C, 20 minutes; 132°C, 8.5 minutes; 134°C, 7.5 minutes and 135°C, 7 minutes.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Murphy -S

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